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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/327,761	06/07/1999	DONALD W. PETERSEN	99.501	5876

7590 10/22/2002

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EXAMINER

WITZ, JEAN C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/22/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/327,761

Applicant(s)

PETERSEN ET AL.

Examiner

Jean C. Witz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,12-21 and 35-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,12-21 and 35-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Response to Arguments

Applicant's arguments filed July 16, 2002 have been fully considered but they are not persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-3, 12-21 and 35-38 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of O'Leary et al. (5,484,601), Yim et al. (5,385,887) and Gertzman et al. (6,030,635) taken as a whole for the reasons of record.

As stated in the previous office action, the Examiner acknowledges that the disclosure of O'Leary does not explicitly disclose the inclusion of calcium sulfate; however, O'Leary teaches that "any variety of substances" may be included in the composition, including what O'Leary describes as "inorganic elements." Applicants assert that the Examiner has taken this disclosure of O'Leary out of context, describing the disclosure of O'Leary as "ambiguous" and argues that the inorganic elements of O'Leary should be limited to components that "have a biological function or be bioactive." Such an interpretation of O'Leary is too narrow. Further, it remains unclear how the inorganic elements of O'Leary would be expected to have a bioactive effect yet the calcium sulfate, clearly inorganic, would not have a similar bioactive effect. Bone is

composed of both organic and inorganic components and calcium is deposited in inorganic form in bone tissue to provide a hardening effect to the bone tissue so that the bone tissue can provide the required support for the organism. It is not seen how this effect is anything other than bioactive. Also, at the time the invention was made, one of ordinary skill in the art would have been aware that the calcium sulfate hemihydrate would eventually be resorbed, and the calcium contained therein would be used to replace the calcium sulfate hemihydrate with bone tissue. Again, it remains unclear how this effect is not "bioactive".

Applicants further argue that "the reasons that Yim discloses for adding calcium sulfate are either inconsistent with the type of compositions that O'Leary intended to form or that the reasons have already been addressed by O'Leary." Applicants suggest that when forming a "putty-like" composition of O'Leary (which includes the use of a thickener), Yim's calcium sulfate would be "unnecessarily redundant" and therefore there is no motivation produce Applicants' composition. Such an argument does not take into consideration the concept of "reduced set-up time" discussed by Yim as a benefit of the inclusion of the calcium sulfate hemihydrate. The degree of flowability of a "putty-like" composition prepared per O'Leary is not in dispute; however, it is clear that regardless of the "putty-like" nature of a composition prior to its implantation in vivo, upon implantation, said composition comes in contact with physiological fluids in varying amounts dependent upon the condition to be treated and these fluids can act to both dilute and dissolve components of the composition such that the composition may not be fully retained at the wound site. Yim teaches (at col. 7, beginning at line 50) that the

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calcium sulfate hemihydrate improves “retention of the formulation at the wound site.”

This is not an issue of the consistency of the formulation prior to implantation; instead, Yim provides motivation to include the calcium sulfate hemihydrate to improve retention of the formulation upon implantation at the wound site due to the known and expected hardening abilities of the calcium sulfate hemihydrate when hydrated. Therefore, it is not seen to be redundant to include the calcium sulfate hemihydrate in the composition of O’Leary.

Applicants assert that the use of demineralized bone as a source of osteogenic proteins is inconsistent with the teaching of Yim, citing Yim, “It is optimal to solubilize the osteogenic protein at concentrations of at least about 1 mg/ml, preferably about 2 to 8 mg/ml, so that a pharmaceutically effective amount of protein can be delivered without undue volumes of carrier being necessary.” (Emphasis added by Applicant in response.) Applicants assert that “[o]ne skilled in the art reading Yim would not be motivated to add demineralized bone material (a source of osteogenic proteins) to Yim’s compositions. Demineralized bone is not in the form of a pharmaceutically acceptable solution. Instead, demineralized bone is formed as solid particles, which Yim expressly wanted to eliminate.” (Emphasis added.) Applicants’ interpretation of a statement of a preferred embodiment as an express statement teaching away from a known alternative is not persuasive. When Yim states “it is optimal”, it appears that Yim is teaching a preferred embodiment; however, there is nothing in the statement that indicates that the use of demineralized bone will be either detrimental nor ineffective.

Finally, Applicants point to Gertzman as a teaching away from the use of calcium sulfate. Applicants point out that Gertzman discloses that "calcium sulfate does not absorb or become remodeled into natural bone so it consequently remains in place indefinitely as a brittle, foreign body in a patient's tissue." Gertzman's assertion regarding calcium sulfate is neither corresponds nor is it supported by the state of the art regarding the use of calcium sulfate in bone implants. Please see the following disclosures cited not as prior art but instead to show the state of the art of calcium sulfate hemihydrate used as in vivo implants of Sidqui et al. (the abstract), Ricci et al. ('636 - paragraph 0003), Ricci et al. ('206 - col. 5, lines 21-22), Randolph et al. ('567 - col. 1, lines 10-25), Grisoni et al. ('127 - col 1, lines 20-27), Snyders, Jr. ('769 - col. 3, lines 3-6). This appears to be Applicants' only argument regarding the Gertzman reference and Applicants did not address the position of the Examiner that bone allograft is an obvious inclusion into a bone graft composition.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

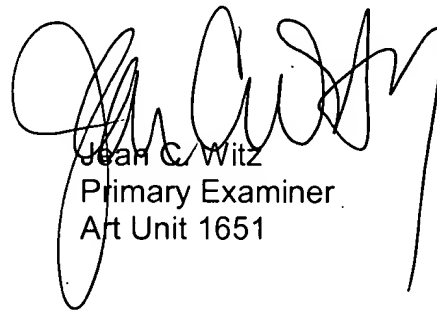
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-Th and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Jean C. Witz
Primary Examiner
Art Unit 1651

October 21, 2002